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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/751,344

12/30/2003

Jens U. Quistgaard

021356-000600US

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11/26/2008

TOWNSEND AND TOWNSEND AND CREW LLP
LIPOSONIX, INC. (70353)
TWO EMABARCADERO CENTER, EIGHTH FLOOR
SAN FRANCISCO, CA 94111

EXAMINER

FERNANDEZ, KATHERINE L

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

11/26/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/751,344	Applicant(s) QUISTGAARD ET AL.	
	Examiner KATHERINE L. FERNANDEZ	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23 and 40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23 and 40 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 1, 2008 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hillstead et al. (US Pub No. 2004/0039312) in view of Salcudean et al. (US Patent No. 6,425,865) in view of Lizzi et al. (US Patent No. 6,846,290) and in view of Peterson et al. (US Patent No. 6,126,619).

Hillstead et al. disclose an apparatus for precise positioning of a medical device comprising an articulating arm (pg. 4, paragraph [0066]); a therapy head attached to the articulating arm (pg. 4, paragraph [0066]), the therapy head including a housing, an array of diagnostic and therapeutic ultrasound transducers contained within the housing (pg. 4, paragraph [0063]; pg. 8, paragraph [0109]), a plurality of detectors (pg. 4, paragraphs [0068]-[0070]), and an electronic data chip (pg. 7, paragraph [0098]); at

least one position sensor located in the therapy head capable of determining the precise position of said therapy head relative to a patient (pg. 4, paragraph [0068]); and a controller wherein the controller utilizes data from said position sensor and the data chip in the therapy head to control the therapy head to maintain the location of the therapy head over the patient body surface (see Abstract; pg. 4, paragraph [0068]; pg. 5, paragraph [0071]; pg. 7, paragraph [0098]).

Although they do not specifically disclose that their articulating arm is robotic, it would have been obvious to one of ordinary skill in the art to have the articulating arm be robotic as it is well known in the art that robotic systems provide more precise and accurate control. However, they do not specifically disclose the specifics of the articulating arm, such as having a base end attached to a base and an unsecured end. Further, although Hillstead et al. do disclose that the transducer may comprise a plurality of independently movable transducer elements and that a variety of mechanical means well known in the art may be employed to drive and control the motion of the transducer elements, they do not specifically disclose that their therapy head includes motors coupled to the array, or that their therapy head includes a water circulation system. Further, although they do disclose that the controller is provided with feedback from the position sensor and from the data chip to maintain the location of the therapy head over the patient body surface (see Abstract; pg. 4, paragraph [0068]; pg. 5, paragraph [0071]; pg. 7, paragraph [0098]), they do not specifically disclose that the controller utilizes the data to control the robotic articulating arm.

Salcudean et al. disclose a method and apparatus to perform ultrasound image acquisition for diagnostic or intervention using a robot to position the ultrasound transducer (column 1, lines 9-11). They disclose that their system includes a robot arm machine carrying the ultrasound probe (which as seen in Figure 2, comprises of a base and a robotic articulating arm having a base end attached to said base and an unsecured end, with the ultrasound probe attached to the unsecured end) (column 6, lines 36-51). The ultrasound probe is removably attached to the unsecured end (column 6, line 63-column 7, line 18). They further disclose that their system includes a controller that controls the motion of the robot arm, wherein their system requires some means of tracking the position of the ultrasound transducer (column 6, lines 36-50). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Hillstead et al. to comprise a base, a robotic articulating arm having a base end attached to said base and an unsecured end, and have the therapy head removably attached to the unsecured end, and further have the controller use the data to control the robotic articulating arm, as Hillstead et al. disclose that their therapy head can be attached to an articulating arm in order to position the therapy head over a treatment region and that data from a position sensor and a data chip is used to track the position the therapy head, and Salcudean et al. teach a robotic articulating arm with the above limitations that successfully positions an ultrasound transducer over the surface of the body of a person and a controller that utilizes data from a transducer position tracking means to successfully control the robotic articulating arm(column 5, lines 7-16).

However, they do not specifically disclose that the therapy head further includes motors coupled to the array or a water circulation system.

Lizzi et al. disclose a method and system for ultrasonic treatment of tissue using a transducer assembly having a first diagnostic transducer and a second therapy transducer (column 1, lines 34-49). They disclose that their transducer assembly includes a diagnostic transducer array, a HIFU transducer array and a coupling cone which is typically filled with fluid for coupling ultrasonic signals to the patient's tissue (column 3, lines 18-35). They further disclose that their transducer assembly includes motors to adjust the orientation and motion of the transducer (column 5, lines 42-58; see Figure 5). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Hillstead et al. in view of Salcudean to include motors coupled to the transducer array, as Hillstead et al. disclose that a variety of mechanical means well known in the art may be employed to drive and control the motion of the transducer elements, and Lizzi et al. disclose the use of motors coupled to the transducer to control the motion of the transducer elements (column 5, lines 42-58; see Figure 5).

However, although the above combined references do disclose the need for a coupling system to couple the transducer to tissue, they do not specifically disclose that the therapy head further includes a water circulation system.

Peterson et al. disclose an ultrasonic medical transducer apparatus and method for coupling ultrasonic energy to a body for medical therapy (column 3, lines 17-21). They disclose that the ultrasonic transducer includes a housing, and means for

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generating ultrasonic waves in response to an electrical signal supplied by an external power source, as well as a front mass disposed in the housing and a radiator for directing the ultrasonic waves into a medical target in a patient (column 3, lines 23-29). A reservoir is provided in the housing for containing a fluid conductive medium, such as water, between the front mass and the body surface of a patient (column 3, lines 31-61; column 6, lines 27-42). They disclose that water is a suitable fluid conductive medium which can be circulated in order to provide protection to healthy tissues (column 3, lines 31-36; column 6, lines 37-42). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the apparatus of the above combined references to have a water circulation system included in the housing, as taught by Peterson et al., as the above combined references require a coupling mechanism to couple the transducer to tissue and Peterson et al. teach a water circulation system that serves as an effective coupling mechanism and provides protection to healthy tissues (column 3, lines 31-36; column 6, lines 37-42).

4. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hillstead et al., Salcudean et al., Lizzi et al. and Peterson et al. as applied to claim 23 above, and further in view of Whitman et al. (US Pub No. 2003/0050654).

As discussed above, the above combined references meet the limitations of claim 23. However, they do not specifically disclose that the controller automatically identifies the therapy head and provides proper motion information to the robotic arm for movement consistent with an operation design for the therapy head, the operational design parameters being incorporated into the data chip. Whitman et al. disclose an

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electromechanical surgical device that includes a remote power console and a flexible shaft wherein the distal end of the flexible shaft may include a second coupling adapted to detachably secure a surgical instrument (pg. 2, paragraph [0039]). They further disclose that a memory unit may be contained within the body portion of the surgical attachment, and the memory unit is configured to store an attachment type identifier (ID) data and other data (pg. 5, paragraph [0050]-[0051]). Whitman et al. further disclose that a controller is configured to read the ID data from the memory unit and that based on the read ID data the controller is configured to read or select from the memory unit an operating program or algorithm corresponding to the type of surgical instrument or attachment connected to the flexible shaft (pg. 5, paragraph [0053]). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of the above combined references to have the controller automatically identify the therapy head and provide proper motion information to the robotic arm for movement consistent with an operation design for the therapy head, the operational design parameters being incorporated into the data chip, as taught by Whitman et al., in order to efficiently identify and operate the therapy head.

Response to Arguments

5. Applicant's arguments with respect to claims 23 and 40 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE L. FERNANDEZ whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768